

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 1 is currently being amended to further clarify claim language and overcome the examiner's rejections under 35 USC §§101 and 112. The amendment to claim 1 also overcomes the anticipatory rejections and places the instant application in a better condition for allowance. The amendments do not raise new issues that would require the examiner to carry out a new search. No new subject matter has been added.

Claims 1-4, 11 and 12 are now pending in this application.

Claim Rejections-35 USC §101:

Claims 1 and 4 are rejected under 35 USC §101 for claiming, as alleged by the examiner, non-statutory subject matter. Claim 1 has been amended to overcome this rejection. As amended, claim 1 recites a method for maintaining and promoting the thickness of hair. The inventive methodology comprises providing a composition capable of increasing the expression of keratinocyte growth factor FGF-7, and applying the composition to the scalp of a subject in need thereof. Since claim 4 depends on amended claim 1, the rejection of claim 4 is moot in light of the amendment to claim 1. Applicants respectfully request the examiner to withdraw this rejection.

Claim Rejections-35 USC §112:

Claim 1 has been amended to overcome the Examiner's rejection under §112, second paragraph. As amended, claim 1 recites the essential steps of a method for maintaining and promoting the thickness of hair in a subject. The claimed method comprises providing a composition capable of increasing the expression of FGF-7, a keratinocyte growth factor and applying the same to a subject in need thereof.

The foregoing amendments overcome the Examiner's 35 USC §112 rejection of claim 1. Since claim 4 now depends on patentable amended claim 1, the §112 rejection of claim 4 is moot. Applicants respectfully request the Examiner to withdraw the rejections of claims 1 and 4.

Claim Rejections-35 USC §102 (b)

Claims 1-4, 11 and 12 are rejected for being allegedly anticipated by Tajima *et al.*, U.S. Patent Application Publication No. 2002/0192177 (“the ‘177 PG PUB”) and Schwarz U.S. Patent No.: 2,960,422. Applicants respectfully traverse this rejection.

Rejection of claim 1 in view of Tajima:

Claim 1 has been amended to recite a method for maintaining and promoting the thickness of hair. The claimed method provides a composition that is capable of increasing the expression of keratinocyte growth factor (FGF-7) in hair follicle cells, upon the application of the composition to the scalp of a subject undergoing treatment. Tajima does not disclose such a method.

The Tajima reference pertains to a hair tonic containing at least one active ingredient and a carrier. According to Tajima, the disclosed hair tonic provides superior *hair loss preventing action as well as hair growth promoting action*. Nowhere does Tajima disclose that its hair tonic composition promotes the ***thickening*** of hair as recited by amended claim 1.

Tajima discloses a test for measuring the ability of its hair tonic to promote the growth of new hair (“hair growth promoting action test”) in mice. According to Tajima, animals in the *resting phase* of the hair growth cycle are used to measure the ability of the hair tonic to *induce* growth of new hair within the test area. Nowhere does Tajima disclose or even suggest that its hair tonic thickens hair. Tajima merely provides a hair tonic for stimulating the growth of new hair.

In addition to promoting hair growth, Tajima discloses its hair tonic to prevent hair loss. See p3, paragraphs 52-55. According to Tajima, subjects complaining of hair loss have a higher proportion of hair roots in the resting phase of the hair cycle. However, the application of the disclosed hair tonic onto the balding scalps of test subjects reduced the ratio of hair roots in the *resting phase* of the hair cycle, thus preventing hair loss.

As mentioned above, nowhere does Tajima disclose its hair tonic to ***thicken hair*** as recited by amended claim 1. In fact, it appears that the examiner has mischaracterized the claimed invention by asserting that increasing the expression of keratinocyte growth factor in hair

follicle cells is merely a new function of a known agent that is known in the prior art. Applicants' claims are not directed to a new function or a mechanism of action for FGF-7, instead amended claim 1 recites a method for increasing the *thickness of hair* using FGF-7. The phrase "hair thickening" refers to *increasing the diameter of the hair* using a composition that has an agent capable of increasing the expression of keratinocyte growth factor (FGF-7). See specification as filed, page 7, lines 1-16. The claimed invention, therefore, provides a novel method for treating hair loss, one that increases the diameter of hair, while Tajima discloses a composition that induces new hair.

To anticipate a claim, a reference must teach each and every element of the claim. As disclosed above, Tajima does not teach a method for maintaining and promoting the thickness of hair, as required by claim 1. Amended claim 1 is therefore patentable over the cited reference. Applicants therefore respectfully request the Examiner to withdraw the rejection of amended claim 1.

Rejection of claim 1 in view of Schwarz:

Amended claim 1 is also patentable over Schwarz. As such, Schwarz does not disclose each and every limitation of amended claim 1. Schwarz discloses an *aqueous hair dressing preparation* that is essentially a solution of nucleic acids. In fact, Schwarz discloses that its hair dressing is manufactured by dissolving deoxy- or ribonucleic acid in water using alkali metal bases such as sodium or potassium hydroxide. There is no mention of using adenosine or its salts as active ingredients of its hair dressing, nor is there any mention of using analogs of adenosine as the active component of its composition. See Examples 1-5 as well as column 2 lines 39-50. Although the examiner alludes that Schwarz discloses preparations containing the nucleic acid adenosine, (col. 2, lines 16 and 52-58) the referenced section is merely a recitation of the four nucleoside bases that are present in RNA. Moreover, Schwarz's hair dressing preparations are to *improve the manageability of hair* on humans and animals. The specification further discloses a method for achieving manageable hair using the disclosed composition.

Thus, contrary to the examiner's assertion, Schwarz does not disclose a method for using its hair dressing to maintain or improve the thickness of hair as recited by the amended claim 1. Schwarz fails to teach each and every element of amended claim 1 and thus does not anticipate

amended claim 1. Furthermore, *hair thickness* refers to the diameter of the hair, and the claimed method discloses a composition that has as its active ingredient an agent capable of increasing the expression of FGF-7 that will promote an increase in the diameter of the hair.

Amended claim 1 is therefore patentable over Schwarz as well as over Tajima. Applicants therefore respectfully request the Examiner to withdraw the rejection of amended claim 1.

Rejections of the Claims that Depend on Claim 1:

Claims 2-4, 11 and 12 are rejected as being anticipated by Tajima and Schwarz. Applicants respectfully disagree. Claims 2-4, 11 and 12 depend on amended claim 1 and incorporate all its limitations. As mentioned above, amended claim 1 is patentable over both the cited references. Thus the claims that depend on amended claim 1 are also patentable over the cited references for at least the same reasons mentioned above for amended claim 1.

Double Patenting:

The examiner has rejected claims 1-4, 11 and 12 on the ground of non-statutory double patenting over claim 1 of U. S. Patent No.: 7,182,939 to Tajima et al. Applicants state that claim 1, as amended, overcomes the double patenting rejection. The Tajima reference claims a hair tonic composition comprising at least one active ingredient and a carrier. However, instant claim 1 is a method claim for promoting and maintaining hair thickness. This is achieved by providing a composition that is capable of increasing FGF-7 expression in hair follicle cells and applying the same on the scalp of subjects in need thereof. Amended claim 1, therefore, is related to a different statutory class of subject matter from that recited by claim 1 of the Tajima reference.

Additionally, claims 1-4, 11 and 12 are provisionally rejected on the ground of non-statutory double patenting over claim 4 of U. S. Patent Application No.: 11/655,134. Applicants will consider filing a terminal disclaimer once patentable subject matter is identified.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264